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Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane Rm. 1061  
Rockville, Maryland 20852

Oct. 28, 1999

To Whom it May Concern,

Regarding Dockets 98N-0313, Surgeon's and Patient Examination Gloves; Reclassification. It is my recommendation that powdered latex gloves should be phased out completely within two years. 120 mgs of powder per glove are a good starting point for the elimination of powdered gloves. Glove powder should be stepped down within a two year time frame until they contain no more than 4 mgs per glove, which is the upper limit for powder-free gloves as per recent ASTM standards. Furthermore, these guidelines should be required, not merely recommended by the FDA.

Powdered latex gloves have been well documented in the medical and scientific literature to be unnecessarily dangerous for both users and patients alike. Continued acceptance of these gloves without a phasing out plan is tolerance of a defective and dangerous product, without sufficient cause.

Respectfully Submitted,

*Rochelle D. Spiker*, MSW, LCSW-C

Rochelle D. Spiker, MSW, LCSW-C  
Executive Director

98N-0313

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